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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,625	10/03/2005	Jeffrey Callister	RADME-70572	9628

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EXAMINER	
HELLING, KAITLYN ELIZABETH	
ART UNIT	PAPER NUMBER
3739	
MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,625	CALLISTER ET AL.	
	Examiner	Art Unit	
	KAITLYN E. HELLING	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. Figure 4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 7-9, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/10494 to Ginsburg et al. (Ginsburg).

Regarding claim 1, Ginsburg teaches a method and apparatus for regional and whole body temperature modification (title and Pg. 42, line 9-Pg. 49, line 4) using a heat exchange catheter (302, Fig. 15) inserted into the body (Fig. 15), the heat exchange catheter having conduits that enable circulation of a heat exchange medium between the heat exchange portion of the catheter and a heating/cooling apparatus for adding or

removing thermal energy (316 and 317, Fig. 15), the heating /cooling apparatus controlled by a controller (300, Fig. 15), providing a temperature probe (Pg. 42, line 22-Pg. 43, line 2), circulating fluid under control of the controller between the heat transfer catheter and the heating/cooling apparatus (Pg. 42, lines 16-19), stopping the flow of fluid through the heat transfer catheter (Pg. 43, lines 13-14 and Pg. 28, lines 2-10), determining and comparing the temperature change while the fluid flow is stopped (Pg. 28, line 22-Pg. 29, line 10), controlling the heating/cooling apparatus in accordance with the comparison to controllably add or remove thermal energy from the heat exchange fluid to heat or cool a patient's blood (Pg. 27, line 22-Pg. 31, line 5).

Regarding claim 2, Ginsburg teaches the method of claim 1 as well as the temperature probe inserted near the heat transfer catheter in the patient (Fig. 15).

Regarding claim 3, Ginsburg teaches the method of claim 1 as well as wherein interrupting the circulating fluid between the heat exchange unit and the heat transfer catheter is controlled by stopping a fluid pump in the master control unit (Pg. 42, lines 16-19, Pg. 43, lines 13-14 and Pg. 28, line 22-Pg. 29, line 10).

Regarding claim 7, Ginsburg teaches the method of claim 1 as well as the temperature probe providing responsive patient data to the processor (Pg. 42, line 22-Pg. 43, line 10).

Regarding claim 8, Ginsburg teaches the method of claim 1 as well as the master controller processor comparing signals from at least two of a plurality of sensors and wither adds heat or adds cooling or stops fluid flow within the heat exchange unit (Pg. 43, lines 8-14).

Regarding claim 9, Ginsburg teaches the method of claim 1 as well as where interrupting the fluid flow between the heat transfer catheter and the heat exchange unit allows the temperature measurements to level off in the heating/cooling region near the temperature probe and the heat transfer catheter, providing an accurate core body temperature measurement (inherent). The examiner asserts that should the fluid flow between the catheter and the heat exchange unit be interrupted the measured temperatures would necessarily level off providing a core temperature measurement.

Regarding claims 38 and 40, Ginsburg teaches an apparatus for regional and whole body temperature modification (title and Pg. 42, line 9-Pg. 49, line 4) using a heat exchange catheter (324, Fig. 16) inserted into the body (Fig. 16), the heat exchange catheter having conduits that enable circulation of a heat exchange medium between the heat exchange portion of the catheter and a heating/cooling apparatus for adding or removing thermal energy (334 and 335, Fig. 16), the heating /cooling apparatus controlled by a controller (341, Fig. 15) responsive to the temperature signal to control the heating/cooling apparatus to add or remove thermal energy from the heat exchange medium (Pg. 46, lines 8-Pg. 47, line 5), and providing a temperature probe (350, Fig. 16 and Pg. 46, line 22-25).

4. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 6,146,411 to Noda et al. (Noda).

Regarding claim 31, Noda teaches a cooling system for an indwelling heat exchange catheter (title) for exchanging heat with the body of a patient for cooling or warming the patient automatically in accordance with the monitored temperature of the

patient (abstract) which includes a catheter for insertion into the body (abstract) having conduits that enable circulation of a heat exchange medium between a heat exchange portion of the catheter (Col. 3, lines 8-19)and a heating/cooling apparatus controlled by a controller (Col. 3, lines 54-59), measuring the patient's temperature via a temperature probe that provides a signal to the controller (Col. 6, line 43-Col. 7, line 24), circulating fluid under control of the controller between the heat transfer catheter and the heating/cooling apparatus so as to regulate the temperature of the patient (Col. 6, line 63-Col. 7, line 5), analyzing the temperature signals received from the temperature probe (Col. 7, lines 9-52), comparing the determined peak temperature to a target temperature (Col. 7, lines 32-52) and controlling the heating/cooling apparatus in accordance with the comparison to controllably add or remove thermal energy from the heat exchange fluid (Col. 6, lines 58-63).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 4-6, 10-13 and 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/10494 to Ginsburg in view of U.S. 6,969,399 B2 to Schock et al. (Schock).

Regarding claims 4 and 5, Ginsburg teaches the method of claim 1, but not the inclusion of interrupting the circulating fluid between the heat exchange unit and heat

transfer catheter by diverting the fluid flow or the diverter unit being a diverter valve. Schock teaches an apparatus for altering the body temperature of a patient (title) which uses a one way valve (179, Fig. 1) between the inlet pump and the heat exchange device. In Schock during regular operation, without the use of the bypass conduit (173, Fig. 1) the fluid passes through to the patient. In Schock during bypass mode, the fluid is diverted from being in contact with the patient (Col. 6, line 51-Col. 7, line 13). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Ginsburg to have included the diverter valve and conduit of Schock as Schock teaches that bypass mode allows for controlling the temperature of the liquid without allowing the liquid to be in contact with the patient (Col. 7, lines 7-13).

Regarding claim 6, Ginsburg in view of Schock teaches the method of claim 4, but not the use of a microprocessor in the master control unit. The use of microprocessors for electronically controlling parameters is well known in the art as a microprocessor is a single chip that typically performs arithmetic and logic operations. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used a microprocessor with the method of Ginsburg and Schock as this is simply a combining of prior art elements according to known methods to yield predictable results (MPEP 2141).

Regarding claims 10 and 12, Ginsburg teaches a method and apparatus for regional and whole body temperature modification (title and Pg. 44, line 22-Pg. 50, line 3) using a temperature probe (348, Fig. 16), a disposable heat exchange catheter capable of being inserted into a patient (324, Fig. 16), the heating /cooling apparatus

controlled by a controller (341, Fig. 16), installing the heat exchange unit into the master control unit and into thermal communication with the heater/cooler unit within (Pg. 45, line 23-Pg. 46, line 16), circulating fluid between the heat transfer catheter and heat exchange unit in the master control unit, therein transferring heat between the heat exchange unit and the heater/cooler unit so as to regulate the temperature of the patient via the heat transfer catheter (Pg. 46, lines 13-16) and periodically interrupting fluid flow from between the heat transfer catheter and the heat exchange unit, monitoring the patient temperature and re-starting the fluid circulation (Pg. 46, lines 17-Pg. 48, line 15). However, Ginsburg does not teach the use of a microprocessor or diverting the circulating fluid to bypass the heat transfer catheter. Schock teaches an apparatus for altering the body temperature of a patient (title) which uses a one way valve (179, Fig. 1) between the inlet pump and the heat exchange device. In Schock during bypass mode, the fluid is diverted from being in contact with the patient (Col. 6, line 51-Col. 7, line 13). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Ginsburg to have included the diverter valve and conduit of Schock as Schock teaches that bypass mode allows for controlling the temperature of the liquid without allowing the liquid to be in contact with the patient (Col. 7, lines 7-13).

With respect to the use of a microprocessor, the use of microprocessors for electronically controlling parameters is well known in the art as a microprocessor is a single chip that typically performs arithmetic and logic operations. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to

have used a microprocessor with the method of Ginsburg and Schock as this is simply a combining of prior art elements according to known methods to yield predictable results (MPEP 2141).

Regarding claim 11, Ginsburg in view of Schock teaches the method of claim 10 with Ginsburg teaching the further limitation of the temperature probe inserted near the heat transfer catheter in the patient and provides responsive patient data (Pg. 46, line 19-Pg. 21).

Regarding claims 13 and 19-21, Ginsburg in view of Schock teaches the method of claims 10 and 12 with Schock teaching the further limitation of the activation of the diverter valve (Col. 6, line 55-Col. 7, line 13). Since applicant does not specify the criticality of using one or the other of the different actuation systems with respect to the others, the examiner asserts that it would have been obvious to one having ordinary skill in the art to have chosen a specific activation as this would simply be a substitution of one known element for another to obtain predictable results (MPEP 2141).

Regarding claims 17 and 18, Ginsburg in view of Schock teaches the method of claim 10 with Ginsburg teaching the further limitation of the temperature probe accurately measuring the temperature (Pg. 42, line 9-Pg.43, line 14) within the heat exchange region after the temperature achieves equilibrium (inherent) and the measured core body temperature used to generate a predictive heating/cooling curve, based on the controller programming (Pg. 27, line 22-Pg. 28, line 10).

Regarding claim 22, Ginsburg teaches a heat transfer catheter system (title and abstract) including a heat transfer catheter insertable into a patient (Fig. 16), a

disposable heat exchange unit (338, Fig. 16 and Pg. 44, line 24) having a fluid flow pathway therewithin (338, Fig. 16) and incorporating an integral pump head (340, Fig. 16) adapted to move fluid through the fluid pathway (Pg. 45, line 25-Pg. 46, line 7), conduits (Pg. 45, lines 14-20) coupled to the heat transfer catheter and heat exchange unit that enable circulation of a heat exchange medium therebetween upon operation of the pump head (Fig. 16), a reusable master control unit (341, Fig. 14) having a heater/cooler (342, Fig. 16) and a pump driver (343, Fig. 16), the disposable heat exchange unit being adapted to couple to the master control unit such that the pump driver engages the integral pump head (Pg. 45, line 23-Pg. 46, line 16) and so that the fluid pathway is in thermal communication with the heater/cooler (Pg. 46, line 11-16). However, Ginsburg does not teach the use of a diverter unit that redirects the fluid pathway, bypassing the heat transfer catheter. Schock teaches an apparatus for altering the body temperature of a patient (title) which uses a one way valve (179, Fig. 1) between the inlet pump and the heat exchange device. In Schock during bypass mode, the fluid is diverted from being in contact with the patient (Col. 6, line 51-Col. 7, line 13). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Ginsburg to have included the diverter valve and conduit of Schock as Schock teaches that bypass mode allows for controlling the temperature of the liquid without allowing the liquid to be in contact with the patient (Col. 7, lines 7-13).

Regarding claim 23, Ginsburg in view of Schock teaches the apparatus of claim 22 with Schock teaching the further limitation of the diverter unit being a diverter valve

activated by the controller (Col. 6, lines 51-66). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Ginsburg in view of Schock with the further limitation of Schock for the diverter unit to be a valve activated by a controller as Schock teaches that such control allows for the control of the fluid temperature (Col. 7, lines 6-10).

Regarding claim 24, Ginsburg in view of Schock teaches the apparatus of claim 22 with Schock teaching the further limitation of the diverter valve being a flow activated valve (Col. 6, line 51-Col. 7, line12). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Ginsburg in view of Schock with the further limitation of Schock for the diverter unit to be a valve activated by a controller as Schock teaches that such control allows for the control of the fluid temperature (Col. 7, lines 6-10).

Regarding claim 25, Ginsburg in view of Schock teaches the system of claim 24 with Ginsburg teaching the further limitations of the heat exchange unit comprising two layers, a stiff back plate and a thinner heat exchange layer bonded thereto, the pattern of bonding between the two layers defining a serpentine pathway (Pg. 45, line 23-Pg. 46, line 7).

Regarding claim 26, Ginsburg in view of Schock teaches the system of claim 25 with Ginsburg teaching the further limitation of the master control unit defining a cavity into which the heat exchange unit couples (Fig. 16), wherein fluid flow through the serpentine pathway causes inflation of the thinner heat exchange layer relative to the

stiff back plate and subsequent compressive retention of the heat exchange unit within the cavity (Pg. 46, lines 8-16).

Regarding claim 27, Ginsburg in view of Schock teaches the system of claim 22 with Ginsburg teaching the heater/cooler comprising a thermoelectric heater/cooler (Pg. 46, lines 11-13).

Regarding claim 28, Ginsburg in view of Schock teaches the system of claim 22 with Ginsburg teaches the plurality of sensors supplying patient data to the master control unit, the master control unit being adapted to operate the heater/cooler based on supplied patient data (Pg. 47, line 6-Pg. 49, line 4).

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/10494 to Ginsburg and U.S. 6,969,399 to Schock as applied to claim 12 above, and further in view of U.S. 6,146,411 to Noda et al. (Noda).

Regarding claims 14-16, Ginsburg in view of Schock teaches the method of claim 12, but not the further limitations of the controller activating the diverter valve periodically or according to a predetermined time and the controller activating the diverter valve based on the previously determined rate of temperature change. Noda teaches the further limitations of the controller activating the diverter valve periodically or according to a predetermined time and the controller activating the diverter valve based on the previously determined rate of temperature change (Col. 1, lines 57-67). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Ginsburg and Schock with the further limitations of Noda that the controller activate the diverter valve as necessary as Noda teaches that using a

controller would alleviate the need for the requirement of constant human intervention and management of the heater/cooler to adjust temperature (Col. 4, lines 35-57).

8. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/10494 to Ginsburg and U.S. 6,969,399 to Schock as applied to claim 10 above, and further in view of U.S. 6,146,411 to Noda et al. (Noda).

Regarding claim 29, Ginsburg in view of Schock teaches the system of claim 28, but fail to teach the further limitation of the sensors being in communication with the master control unit and an alarm system in the feedback scheme. Noda teaches the further limitation of the sensors being in communication with the master control unit (Col. 7, lines 14-24) and an alarm system in the feedback scheme (Col. 7, lines 31-52) of the cooling system for an indwelling heat exchange catheter (title). It would have been obvious to one having ordinary skill in the art at the time of the invention to have further modified Ginsburg and Schock to include the alarm of Noda as Noda teaches that that temperature deviation is indicative of certain physiological activity of which the physician should be apprised (Col. 7, lines 38-41).

With respect to the use of a microprocessor, the use of microprocessors for electronically controlling parameters is well known in the art as a microprocessor is a single chip that typically performs arithmetic and logic operations. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used a microprocessor with the method of Ginsburg and Schock as this is simply a combining of prior art elements according to known methods to yield predictable results (MPEP 2141).

Regarding claim 30, Ginsburg in view of Schock teaches the system of claim 29 with Ginsburg teaching the further limitation of the steps of adding or removing heat from the system in a controlled manner (Pg. 27, line 22-Pg. 31, line 5). While neither Ginsburg, Schock nor Noda teach the use of a microprocessor, the examiner asserts that the use of microprocessors for electronically controlling parameters and performing arithmetic and logic operations is well know. Therefore it would have been obvious to have further modified Ginsburg and Schock to have included a microprocessor as this is a combination of prior art elements according to known methods to yield predictable results (MPEP2141).

9. Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,146,411 to Noda et al. (Noda).

Regarding claims 32 and 33, Noda teaches the method of claim 31 as well as outlining the steps necessary to analyze the temperature signals (Col. 4, lines 38-57 and Col. 6, line 43-Col. 7, line 51), but not the limitations of implementing and repeating the analysis at predetermined intervals. While Noda does not explicitly disclose all of these limitations, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used the analysis of Noda as Noda teaches that there is a temperature correlation between the probe and catheter placement that can be used to program the temperature control algorithm employed by the temperature controller to achieve a target temperature or temperature range (Col. 7, lines 8-14). Similarly it would have been obvious to one having ordinary skill in the art at the time of the invention to have regularly implemented and repeated the temperature analysis as

Noda teaches that temperature deviations generally indicate physiological activity of which the physician should be apprised (Col. 7, lines 31-41).

Regarding claims 34-37, Noda outlines the steps necessary to analyze the temperature signals (Col. 4, lines 38-57 and Col. 6, line 43-Col. 7, line 51), but does not explicitly teach the limitations of the offset value calculations. While Noda does not teach the calculating the offset values either statically or dynamically, Noda does teach that the controller will adjust the temperature of the circulating fluid in response to the temperature of the patient when compared to the temperature of the cooling fluid and the predetermined ranges of acceptable temperatures for therapeutic benefit (Col. 4, lines 37-57 and Col. 6, line 43-Col. 7, line 52). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have calculated the offset values in order to adjust the temperature of the cooling/heating fluid being circulated as taught by Noda (Col. 4, lines 37-57 and Col. 6, line 43-Col. 7, line 52).

10. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/10494 to Ginsburg et al. and U.S. 6,146,411 to Noda et al. (Noda).

Regarding claim 39, Ginsburg teaches the system of claims 38 but not the outlining of steps necessary to analyze the temperature signals. Noda teaches the outlining the steps necessary to analyze the temperature signals (Col. 4, lines 38-57 and Col. 6, line 43-Col. 7, line 51), but not the limitations of implementing and repeating the analysis at predetermined intervals. While Noda does not explicitly disclose all of these limitations, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used the analysis of Noda as Noda teaches that there is a

temperature correlation between the probe and catheter placement that can be used to program the temperature control algorithm employed by the temperature controller to achieve a target temperature or temperature range (Col. 7, lines 8-14). Similarly it would have been obvious to one having ordinary skill in the art at the time of the invention to have regularly implemented and repeated the temperature analysis as Noda teaches that temperature deviations generally indicate physiological activity of which the physician should be apprised (Col. 7, lines 31-41).

Regarding claim 41, Ginsburg teaches the system of claim 40 but not the outlining of steps necessary to analyze the temperature signals. Noda teaches a processor and a memory (Col.4, lines 47-51) the outlining the steps necessary to analyze the temperature signals (Col. 4, lines 38-57 and Col. 6, line 43-Col. 7, line 51), but not the limitations of implementing and repeating the analysis at predetermined intervals. While Noda does not explicitly disclose all of these limitations, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used the analysis of Noda as Noda teaches that there is a temperature correlation between the probe and catheter placement that can be used to program the temperature control algorithm employed by the temperature controller to achieve a target temperature or temperature range (Col. 7, lines 8-14). Similarly it would have been obvious to one having ordinary skill in the art at the time of the invention to have regularly implemented and repeated the temperature analysis as Noda teaches that temperature deviations generally indicate physiological activity of which the physician should be apprised (Col. 7, lines 31-41).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-6,7-13, 17-28 and 38 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. U.S. 6,620,188 B1 in view of U.S. 6,969,699 B2 to Schock et al. The claims of the application being examined differ from the patented material in the addition of a flow diverter. However, Schock teaches the use of a flow diverter to redirect the cooling fluid away from the cooling device/catheter. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have included the flow diverter of Schock with Ginsburg as Schock teaches that the concept of a diverter or bypass valve for temperature control is known in the art and is advantageous for controlling the amount of heating/cooling applied to the patient (Col. 6, line 51-Col. 7, line 13).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. 6,620,187 B2 to Cason et al. teaches a patient temperature control system with make-up fluid supply, U.S. 5,862,675 to Scaringe et al. teaches an electrically-driven cooling/heating system utilizing circulated liquid, and U.S. 3,425,419 to A. A. Dato teaches a method for lowering and raising the temperature of the human body.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 7:30 a.m. to 5:00 p.m. EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/
Primary Examiner, Art Unit 3739

/KAITLYN E HELLING/
Examiner, Art Unit 3739